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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,733	06/12/2000	CHARLES ZUKER	02307E-085110US	6739

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EXAMINER	
MYERS, CARLA J	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/463,733	ZUKER, CHARLES	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 5-13, 15, 17,19,20,and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,15,17,19,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed February 28, 2008. Applicant's arguments have been fully considered but are not persuasive to place the pending claims in condition for allowance.

All rejections not reiterated herein are hereby withdrawn. In particular, the objection to the specification as failing to provide proper antecedent basis for the claimed subject matter has been obviated by the amendment to the claims. The rejection of the claims under 35 U.S.C. 112, first paragraph, written description, has been obviated by the amendment to the claims to omit the reference to "mutant Drosophila RDGC phosphatase." The previous rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Byk in view of Zuker , Fang and Steele has been overcome by the amendment to the claims to recite an additional step of providing a second sample comprising a mutant rhodopsin lacking the last 18 amino acids of the cytoplasmic terminus

Claims 1, 5-13, 15, 17, 19, 20, and 22 are pending and have been examined herein.

This action contains new grounds of rejection necessitated by Applicant's amendments to the claims and is made final.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 – New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-13, 15, 17, 19, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not appear to provide basis for the amendment to the claims to recite a method of screening for modulators of RDGC GPCR phosphatase activity wherein the method includes providing a second sample containing a mutant rhodopsin lacking the last 18 amino acids at the cytoplasmic terminus and a Drosophila RDGC phosphatase comprising SEQ ID NO: 1.

In the response filed February 28, 2008, Applicants point to page 44, lines 11-18 as providing support for this amendment.

However, the specification at page 44 discloses a single mutant rhodopsin protein in which the COOH-terminal 18 amino acids have been deleted - i.e., Rh1Δ356. The specification (pages 43-44) teaches an assay in which "RDGC was analyzed biochemically, physiologically, and genetically to determine its activity as a GPCR phosphatase." In these assays, transgenic flies expressing the truncated rhodopsin were analyzed, as were flies expressing wildtype rhodopsin. The specification reports that "(t)he truncated receptor was expressed in near normal amounts and the cells

displayed normal light response. Rhodopsin was not hyperphosphorylated in Rh1Δ356 flies."

However, the specification does not disclose the use of the truncated rhodopsin mutant in methods of screening for modulators of RDGC phosphatase activity. There are no teachings in the specification of a method wherein steps are performed which screen for a modulator of RDGC GPCR phosphatase activity in a first sample that is contacted with a test compound, and wherein simultaneously or previously or subsequently a second sample is further provided which contains a mutant rhodopsin lacking the cytoplasmic terminal 18 amino acids and a Drosophila GPCR phosphatase comprising SEQ ID NO: 1. The disclosure at page 44 of the specification of a transgenic fly comprising Rh1Δ356 does not provide basis for the distinct concept of a screening assay, performed in vitro or in cells, for modulators of RDGC GPCR phosphatase activity wherein the assay includes performing a step of providing sample comprising a mutant rhodopsin lacking the cytoplasmic terminal 18 amino acids and a Drosophila GPCR phosphatase comprising SEQ ID NO: 1.

Additionally, the claims encompass the use of a "mutant rhodopsin lacking the last 18 amino acids at the cytoplasmic terminus as compared to wild type." Since the claims do not define the "wild type" and do not define the length of the mutant rhodopsin, the claims encompass mutants in which more than 18 amino acids are deleted from the COOH-terminus. That is, mutants in which 19 or 20 or 21, etc amino acids are deleted from the cytopasmic terminus constitute mutants lacking the last 18 amino acids at the cytopasmic terminus as compared to a wildtype. However, the

specification provides basis only for a single rhodopsin mutant – i.e., mutant Rh1Δ356, in which only the COOH-terminal 18 amino acids have been deleted.

Regarding the amendment to step iv) to recite "detecting a change in the level of Drosophila RDGC GPCR phosphatase activity," the specification does not provide support for this recitation. The specification provides support only for screening methods in which the results obtained with a test sample are compared to those obtained with a control sample that does not receive the test compound (see, e.g., page 22). The specification does not provide support for the concept of detecting any change in the level of phosphatase activity in the first sample alone, for example, by comparing the first sample to any other unspecified sample. To the extent that the change in level of phosphatase activity is detected by a comparison of the first and second sample, the specification also does not provide support for this concept. It is acknowledged that the specification provides basis for the concept of screening for modulators of RDGC GPCR phosphatase activity in which a mutant rhodopsin is used as a substrate for RDGC phosphatase. However, the mutant rhodopsin lacking the C-terminal 18 amino acids is missing the residues which become phosphorylated and thereby the mutant rhodopsin is not hyperphosphorylated. The specification does not teach the concept that may be encompassed by the present claims in which the results obtained in a second sample containing the truncated rhodopsin are compared to results obtained in a first sample containing rhodopsin to detect "a change in level of Drosphila RDGC GPCR phosphatase" to thereby identify a modulator of RDGC GPCR phosphatase activity.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-13, 15, 17, 19, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-13, 15, 17, 19, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the steps which establish a nexus between the step of providing a second sample comprising a mutant rhodopsin and Drosophila RDGC phosphatase and the remaining steps of the method of screening for modulators of RDGC GPCR phosphatase activity. The claims as amended merely recite a step of providing said second sample but do not recite any method steps in which the second sample is utilized in the screening assay for modulators of RDGC phosphatase activity. Nor do the claims recite any type of relationship between the first and second samples. Accordingly, the claims omit essential steps and elements.

Further, claims 1, 5-13, 15, 17, 18, 20 and 22 are indefinite over the recitation of "detecting a change in level of Drosophila RDGC GPCR phosphatase activity." The claims do not set forth what the level of activity is being compared to and do not recite any of the essential steps that would allow one to ascertain a change in the level of activity. Thereby, the claims are indefinite because it is unclear as to what constitutes a

change in Drosophila RDGC GPCR phosphatase activity and because the claims omit the essential steps required to detect a change in the level of Drosophila RDGC GPCR phosphatase activity.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634